

**OTC Ingredient List**  
*Updated May 2005*

<b>Ingredient</b>	<b>Review Panel</b>	<b>Report</b>	<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
<b>paba</b> [see aminobenzoic acid]	=====	=====	=====	=====	=====	=====
<b>padimate a</b>						
miscellaneous external external analgesic			fever blister (topical)		defer	defer pending
miscellaneous external skin protectant			fever blister (topical)		defer	defer pending
topical analgesic	sunscreen		sunscreen	I	IISE	[64 FR 27682]
topical analgesic	sunscreen		sunscreen	I	IISE	[64 FR 27682]
<b>padimate o</b>						
topical analgesic	sunscreen		sunscreen	I	I	352.10(m)
<b>pamabrom</b>						
miscellaneous internal menstrual/diuretic			diuretic	I	I	pending
<b>pancreatin</b>						
miscellaneous internal digestive aid			digestive aid (ippuad)	IIIE	IIIE	310.545(a)(8)(i)
miscellaneous internal digestive aid			digestive aid (intestinal distress)	IIIIE	IIIIE	310.545(a)(8)(i)
miscellaneous internal exocrine pancreatic insufficiency			exocrine pancreatic insufficiency	I	I	310.543(a)
miscellaneous internal weight control			anorectic	IISE	IISE	310.545(a)(20)
<b>pancrelipase</b>						
miscellaneous internal digestive aid			digestive aid (intestinal distress)	IIIIE	IIIIE	310.545(a)(8)(i)
miscellaneous internal digestive aid			digestive aid (ippuad)	IIE	IIE	310.545(a)(8)(i)

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	miscellaneous internal	exocrine pancreatic insufficiency	exocrine pancreatic insufficiency	I	I	310.543(a)
<b>panthenol</b>						
	miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
	miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
	miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
	miscellaneous external	external analgesic	insect bite/sting	n/a	IIIIE	310.545(a)(10)(vi)
	miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IIIIE	310.545(a)(10)(vii)
	miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
	miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)
	miscellaneous external	corn/callus remover	corn/callus remover	IISE	IISE	[55 FR 33261]
<b>pantothenic acid</b>						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>papain</b>						
	contraceptive/vaginal	vaginal	lowers surface tension mucolytic effects	IIIIE	withdraw	n/a
	miscellaneous internal	digestive aid	digestive aid (intestinal distress)	IIE	IIE	310.545(a)(8)(i)
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>papaya enzymes</b>						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)

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<b>papaya, natural</b>						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
<b>para-chloromercuriphenol</b>						
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	IISE	310.545(a)(27)(ii)
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	mercury		first aid antiseptic	IISE	n/a	310.545(a)(27)(i)
miscellaneous external	mercury		antiseptic	IISE	IISE	310.545(a)(27)(i)
miscellaneous external	skin protectant		diaper rash	defer	n/a	310.545(a)(27)(ii)
<b>para-t-butyl-m-cresol</b>						
miscellaneous external	external analgesic		astringent	IISE	n/a	n/a
miscellaneous external	skin protectant		astringent	IISE	IISE	310.545(a)(18)(ii)
<b>para-tertiary-butyl-meta-cresol</b> [see para-t-butyl-m-cresol]	====	=====	=====	====	=====	=====
<b>paraffin</b>						
miscellaneous external	external analgesic		fever blister (topical)	defer	n/a	n/a
miscellaneous external	skin protectant		fever blister (topical)	defer	n/a	n/a
ophthalmic	ophthalmic		emollient	I	I	349.14(b)(3)

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<b>para-t-butyl-m-cresol</b>						
miscellaneous external	external analgesic		astringent	IISE	n/a	n/a
miscellaneous external	skin protectant		astringent	IISE	IISE	310.545(a)(18)(ii)
<b>para-tertiary-butyl-meta-cresol [see p-t-butyl-m-cresol]</b>						
=====	=====	=====	=====	=====	=====	=====
<b>paregoric</b>						
laxative	antidiarrheal		antidiarrheal	I	IIISE	310.545(a)(3)(i)
<b>parethoxycaine hydrochloride</b>						
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
miscellaneous external	skin protectant		poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
<b>parsley</b>						
miscellaneous internal	menstrual/diuretic		diuretic	n/a	IISE	310.545(a)(24)(i)
<b>passion flower extract</b>						
sedative	nighttime sleep aid		sleep aid	IIE	IIE	[54 FR 6826]
<b>pectin</b>						
laxative	antidiarrheal		antidiarrheal	IIIIE	IIIIE	310.545(a)(3)(ii)
miscellaneous external	external analgesic		fever blister (topical)	defer	IIISE	310.545(a)(10)(v)
miscellaneous external	skin protectant		fever blister (topical)	defer	defer	pending
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)

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	oral cavity	oral health care	demulcent	I	I	pending
<b>pega palo</b>						
miscellaneous internal	aphrodisiac		aphrodisiac	IIE	IIE	310.528(a)
<b>peppermint</b>						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
<b>peppermint oil</b>						
cough/cold	cough/cold (antitussive)		antitussive (topical/inhalant)	IIIIE	IIIIE	[52 FR 30054]
cough/cold	cough/cold (expectorant)		expectorant (lozenge)	IIIIE	IIIIE	310.545(a)(6)(iii)
cough/cold	cough/cold (expectorant)		expectorant (topical/inhalant)	IIIIE	IIIIE	310.545(a)(6)(iii)
cough/cold	cough/cold (nasal decongestant)		nasal decongestant (inhalant room spray)	IIIIE	IIIIE	[59 FR 43408]
cough/cold	cough/cold (nasal decongestant)		nasal decongestant (lozenge)	IIIIE	IIIIE	[59 FR 43408]
cough/cold	cough/cold (nasal decongestant)		nasal decongestant (mouthwash)	IIIIE	IIIIE	310.545(a)(6)(ii)(A)
cough/cold	cough/cold (nasal decongestant)		nasal decongestant (topical/inhalant)	IIIIE	IIIIE	[59 FR 43408]
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		astringent	IIE	n/a	n/a
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	external analgesic		fever blister (topical)	defer	n/a	n/a
miscellaneous external	external analgesic		insect bite/sting	IIE	IIE	310.545(a)(10)(vi)

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		miscellaneous external skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)	
		miscellaneous external skin protectant	diaper rash	defer	n/a	pending	
		miscellaneous external skin protectant	fever blister (topical)	defer	n/a	n/a	
		miscellaneous external skin protectant	insect bite/sting	IISE	IISE	310.545(a)(18)(v)	
		miscellaneous internal digestive aid	digestive aid (ippuad)	IIIIE	IIIIE	310.545(a)(8)(i)	
<b>peppermint oil and sage oil</b>							
====		gingivitis/plaque	antiplaque/gingivitis	n/a	IIIIE	pending	
<b>peppermint spirit</b>							
		miscellaneous internal digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)	
		miscellaneous internal menstrual/diuretic	premenstrual/menstrual period	n/a	IISE	310.545(a)(24)(i)	
<b>pepsin</b>							
		miscellaneous internal digestive aid	digestive aid (ippuad)	IIIE	IIIE	310.545(a)(8)(i)	
		miscellaneous internal digestive aid	digestive aid (intestinal distress)	IIIE	IIIE	310.545(a)(8)(i)	
		miscellaneous internal stomach acidifier	stomach acidifier	IIIE	IIIE	310.540(a)	
		miscellaneous internal weight control	anorectic	IISE	IISE	310.545(a)(20)	
<b>pepsin, essence</b>							
		miscellaneous internal menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)	
<b>peruvian balsam</b>							
		hemorrhoidal	anorectal	wound healing agent (intrarectal)	IIIIE	IIIIE	310.545(a)(26)(x)

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	hemorrhoidal	anorectal	wound healing agent (external)	IIIIE	IIIIE	310.545(a)(26)(x)
	miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
	miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
	miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
	miscellaneous external	skin protectant	diaper rash	defer	IIIIE	pending
<b>peruvian balsam oil</b>						
	miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
	miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
	miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
	miscellaneous external	skin protectant	diaper rash	defer	IIIIE	pending
<b>petrolatum</b>						
	hemorrhoidal	anorectal	protectant (external)	n/a	I	346.14(8)
	hemorrhoidal	anorectal	protectant (intrarectal)	n/a	I	346.14(8)
	miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
	miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
	miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)
	miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
	miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	n/a
	miscellaneous external	skin protectant	diaper rash	defer	I	pending

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	miscellaneous external	skin protectant	fever blister (topical)	defer	I	pending
	ophthalmic	ophthalmic	emollient	n/a	I	349.14(b)(4)
	topical analgesic	skin protectant	skin protectant	I	I	347.10(m)
<b>petrolatum, red</b>						
	topical analgesic	sunscreen	sunscreen	I	I	310.545(a)(29)
<b>petrolatum, white</b>						
	hemorrhoidal	anorectal	protectant (intrarectal)	I	I	346.14(10)
	hemorrhoidal	anorectal	protectant (external)	I	I	346.14(10)
	miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
	miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
	miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
	miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	n/a
	miscellaneous external	skin protectant	diaper rash	defer	I	pending
	miscellaneous external	skin protectant	fever blister (topical)	defer	I	pending
	ophthalmic	ophthalmic	emollient	I	I	349.14(b)(6)
	topical analgesic	skin protectant	skin protectant	I	I	347.10(r)
<b>phenacaine hydrochloride</b>						
	hemorrhoidal	anorectal	anesthetic (external)	IIS	IIS	310.545(a)(26)(vi)
	hemorrhoidal	anorectal	anesthetic (intrarectal)	IIS	IIS	310.545(a)(26)(vi)

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<b>phenacetin</b>						
internal analgesic	internal analgesic		analgesic	IIS	IIS	310.545(a)(23)(i)
internal analgesic	internal analgesic		antipyretic	IIS	IIS	310.545(a)(23)(i)
internal analgesic	internal analgesic		antirheumatic	IISE	not OTC	310.545(a)(23)(i)
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
miscellaneous internal	menstrual/diuretic		analgesic	IIS	IISE	310.545(a)(24)(i)
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
<b>phenindamine tartrate</b>						
cough/cold	cough/cold (antihistamine)		antihistamine	I	I	341.12(i)
miscellaneous internal	menstrual/diuretic		menstrual	n/a	IISE	310.545(a)(24)(i)
<b>pheniramine maleate</b>						
cough/cold	cough/cold (antihistamine)		antihistamine	I	I	341.12(j)
internal analgesic	internal analgesic		analgesic adjuvant	IIIIE	IIIIE	310.545(a)(23)(i)
internal analgesic	internal analgesic		antipyretic adjuvant	IIIIE	IIIIE	310.545(a)(23)(i)
internal analgesic	internal analgesic		antirheumatic adjuvant	IIIIE	n/a	310.545(a)(23)(i)
<b>phenobarbital</b>						
cough/cold	cough/cold (miscellaneous)		corrective	IIIIE	IIS	pending
<b>phenol</b>						
antimicrobial I	antimicrobial		first aid antiseptic	n/a	n/a	pending

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antimicrobial I	antimicrobial	surgical hand scrub	IIIIE	IIIIE	pending	
antimicrobial I	antimicrobial	surgical hand scrub	IIS	IIS	pending	
antimicrobial I	antimicrobial	skin wound cleanser	IIIIE	IIIIE	pending	
antimicrobial I	antimicrobial	skin antiseptic	IIS	IIS	pending	
antimicrobial I	antimicrobial	skin wound protectant	IIIIE	IIIIE	pending	
antimicrobial I	antimicrobial	antimicrobial soap	IIS	IIS	pending	
antimicrobial I	antimicrobial	antimicrobial soap	IIIIE	IIIIE	pending	
antimicrobial I	antimicrobial	skin wound protectant	n/a	IIISE	pending	
antimicrobial I	antimicrobial	skin wound protectant	IIS	IIS	pending	
antimicrobial I	antimicrobial	preoperative skin prep	IIS	IIS	pending	
antimicrobial I	antimicrobial	preoperative skin prep	IIIIE	IIIIE	pending	
antimicrobial I	antimicrobial	skin wound cleanser	IIS	IIS	pending	
antimicrobial I	antimicrobial	first aid antiseptic	n/a	I	pending	
antimicrobial I	antimicrobial	skin antiseptic	IIIIE	IIIIE	pending	
antimicrobial I	antimicrobial	health care personnel handwash	IIIIE	IIIIE	pending	
antimicrobial I	antimicrobial	health care personnel handwash	IIS	IIS	pending	
antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)	
antimicrobial II	antifungal	antifungal	IISE	IIISE	310.545(a)(22)(ii)	
contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw n/a		

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dental	relief of oral discomfort	toothache relief	IIIE	IIIE	pending	
dental	relief of oral discomfort	oral mucosal analgesic	I	I	pending	
hemorrhoidal	anorectal	antiseptic (intrarectal)	IISE	IISE	310.545(a)(26)(ii)	
hemorrhoidal	anorectal	antiseptic (external)	IISE	IISE	310.545(a)(26)(ii)	
miscellaneous external	antifungal	diaper rash	defer	IISE	310.545(a)(22)(ii)	
miscellaneous external	antimicrobial	diaper rash	defer	IISE	310.545(a)(27)(ii)	
miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIIIE	IIIIE	310.545(a)(7)	
miscellaneous external	external analgesic	astringent	IISE	n/a	n/a	
miscellaneous external	external analgesic	diaper rash	defer	IISE	310.545(a)(10)(iv)	
miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending	
miscellaneous external	external analgesic	insect bite/sting	IISE	I	pending	
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	I	pending	
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)	
miscellaneous external	skin protectant	diaper rash	defer	n/a	310.545(a)(27)(ii)	
miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	310.545(a)(18)(v)(A)	
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)	
oral cavity	oral health care	antimicrobial	IIIIE	IIIIE	pending	
oral cavity	oral health care	analgesic/anesthetic	I	I	pending	

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	topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending
<b>phenol sulfonate</b>						
	laxative	antiemetic	antiemetic	IIIIE	IIE	[52 FR 15891]
	topical analgesic	sunscreen	sunscreen	n/a	n/a	[64 FR 27682]
<b>phenolate sodium</b>						
	=====	external analgesic	poison ivy/oak/sumac	n/a	I	pending
	antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)
	antimicrobial II	antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)
	contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw n/a	
	dental	relief of oral discomfort	toothache relief	IIISE	IIISE	pending
	dental	relief of oral discomfort	oral mucosal analgesic	I	I	pending
	hemorrhoidal	anorectal	antiseptic (external)	IIISE	IIISE	310.545(a)(26)(ii)
	hemorrhoidal	anorectal	antiseptic (intrarectal)	IIISE	IIISE	310.545(a)(26)(ii)
	miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIIIE	IIIIE	310.545(a)(7)
	miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending
	oral cavity	oral health care	antimicrobial	IIIIE	IIIIE	pending
	topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending
<b>phenolathalain, yellow</b>						
	laxative	laxative	stimulant laxative	I	I/IIS	310.545(a)(12)(iv)(B)

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<b>phenolphthalein, white</b>						
laxative	laxative		stimulant laxative	I	I/IIS	310.545(a)(12)(iv)(B)
<b>phenolphthalein, white</b> [see phenolphthalein]	=====	=====	=====	=====	=====	=====
<b>phenoxyacetic acid</b>						
miscellaneous external	corn/callus remover		corn/callus remover	IIIIE	IIIIE	[55 FR 33261]
<b>phenyl salicylate</b>						
antimicrobial II	acne		acne	IIE	IIE	310.545(a)(1)
antimicrobial II	antifungal		antifungal	IIISE	IIISE	310.545(a)(22)(ii)
laxative	antidiarrheal		antidiarrheal	IIIIE	IIIIE	310.545(a)(3)(i)
laxative	antiemetic		antiemetic	IIIIE	IIE	[52 FR 15891]
miscellaneous external	corn/callus remover		corn/callus remover	IISE	IISE	[55 FR 33261]
miscellaneous internal	menstrual/diuretic		diuretic	n/a	IISE	310.545(a)(24)(i)
<b>phenylalanine</b>						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
<b>phenylbenzimidazole sulfonic acid</b> [see ensulizole]	=====	=====	=====	=====	=====	=====
<b>phenylephrine hydrochloride</b>						
cough/cold	cough/cold (nasal decongestant)		nasal decongestant (oral)	I	I	341.20(a)(1)

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cough/cold	cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	I	I	341.20(b)(8)
hemorrhoidal	anorectal		vasoconstrictor (intrarectal)	I	I	346.10(d)
hemorrhoidal	anorectal		vasoconstrictor (external)	I	I	346.10(d)
oral cavity	oral health care		oral mucosal decongestant	IIIIE	IIIIE	pending
<b>phenylephrine hydrochloride (0.08 to 0.2%)</b>						
ophthalmic	ophthalmic		vasoconstrictor	I	I	349.18(c)
<b>phenylephrine hydrochloride (less than 0.08%)</b>						
ophthalmic	ophthalmic		vasoconstrictor	IIIIE	IIIIE	310.545(a)(21)(v)
<b>phenylmercuric acetate</b>						
contraceptive/vaginal	contraceptive (vaginal)		contraceptive	IIS	withdraw	310.545(a)(28)
<b>phenylmercuric nitrate</b>						
contraceptive/vaginal	contraceptive (vaginal)		contraceptive	IIS	withdraw	310.545(a)(28)
miscellaneous external antifungal			diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external antimicrobial			diaper rash	defer	n/a	pending
miscellaneous external mercury			first aid antiseptic	n/a	IIIIE	310.545(a)(27)(i)
miscellaneous external external analgesic			diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external skin protectant			diaper rash	defer	n/a	pending
miscellaneous external mercury			antiseptic	IISE	IISE	310.545(a)(27)(i)

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<b>Ingredient</b>	<b>Review Panel</b>	<b>Report</b>	<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
<b>phenylpropanolamine bitartrate</b>						
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (oral)	I	I		pending
<b>phenylpropanolamine hydrochloride</b>						
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (oral)	I	I		pending
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	IIIIE	I		pending
miscellaneous internal	weight control	anorectic	I	I/IIS		pending
oral cavity	oral health care	oral mucosal decongestant	IIIIE	IIIIE		pending
<b>phenylpropanolamine maleate</b>						
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (oral)	I	I		pending
<b>phenyltoloxamine citrate</b>						
internal analgesic	internal analgesic	antipyretic adjuvant	IIIIE	IIIIE		pending
internal analgesic	internal analgesic	antirheumatic adjuvant	IIIIE	n/a		n/a
<b>phenyltoloxamine citrate [see phenyltoloxamine dihydrogen citrate]</b>						
=====	=====	=====	=====	=====	=====	=====
<b>phenyltoloxamine dihydrogen citrate</b>						
cough/cold	cough/cold (antihistamine)	antihistamine	IIIIE	IIIIE		310.545(a)(6)(i)(B)
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE		310.545(a)(18)(vi)
sedative	nighttime sleep aid	sleep aid	IIISE	IIISE		[54 FR 6826]
sedative	nighttime sleep aid	sleep aid	IIISE	IIISE		[54 FR 6826]

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	miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
<b>phosphate, disodium</b> [see sodium phosphate, dibasic]	=====	=====	=====	=====	=====	=====
<b>phosphate, monosodium</b> [see sodium phosphate, monobasic]	=====	=====	=====	=====	=====	=====
<b>phosphorated carbohydrate</b>	laxative	antiemetic	antiemetic	IIIIE	IIIIE	52 FR 15891]
<b>phosphoric acid</b>	dental	anticaries	anticavity agent	IIE	n/a	310.545(a)(2)(ii)
<b>phosphorus</b>	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>phytolacca</b>	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>picrotoxin</b>	miscellaneous external	pediculicide	pediculicide	IISE	IISE	310.545(a)(25)(i)
<b>pine tar</b>	cough/cold	cough/cold (expectorant)	expectorant	IIIIE	IIIIE	310.545(a)(6)(iii)
	miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)
	miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIIIE	IIIIE	310.545(a)(7)

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<b>pine tar syrup</b> cough/cold	cough/cold (expectorant)	expectorant	IIIIE	IIIIE	310.545(a)(6)(iii)
<b>pineapple enzymes</b> miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>piperazine citrate</b> miscellaneous internal	antihelmintic	anthelmintic	IIS	IIS	[51 FR 27758]
<b>piperocaine hydrochloride</b> ophthalmic	ophthalmic	analgesic/anesthetic	IIS	IIS	310.545(a)(21)(i)
<b>pipsissewa</b> miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
<b>piscidia erythrina</b> miscellaneous internal	menstrual/diuretic	dysmenorrhea	IIE	IIE	310.545(a)(24)(i)
<b>plantago ovata husks</b> [see psyllium husk] =====	=====	=====	=====	=====	=====
<b>plantago seed</b> laxative	laxative	bulk laxative	I	I	pending
miscellaneous internal	weight control	anorectic	IIIIE	IISE	310.545(a)(20)
<b>plantago seed husks</b> [see psyllium husk ] =====	=====	=====	=====	=====	=====

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<b>plantago seed, blond</b> [see plantago seed]	=====	=====	=====	=====	=====	=====
<b>podophyllum resin</b>	laxative	laxative	stimulant laxative	IIS	IIS	310.545(a)(12)(iv)(A)
<b>poloxalkol</b> [see polxamer 188]	=====	=====	=====	=====	=====	=====
<b>poloxamer 188</b>	antimicrobial I	antimicrobial	skin wound cleanser	n/a	I	pending
	laxative	laxative	stool softener	IIIIE	IIIIE	310.545(a)(12)(iii)
<b>poloxamer 407</b>	dental	relief of oral discomfort	tooth desensitizer (in combination only)	IIIIE	IIIIE	pending
<b>poloxamer-iodine complex</b>	antimicrobial I	antimicrobial	surgical hand scrub	IIISE	IIISE	pending
	antimicrobial I	antimicrobial	preoperative skin prep	IIISE	IIISE	pending
	antimicrobial I	antimicrobial	antimicrobial soap	n/a	IIISE	pending
	antimicrobial I	antimicrobial	skin wound cleanser	IIISE	IIISE	pending
	antimicrobial I	antimicrobial	skin antiseptic	IIISE	IIISE	pending
	antimicrobial I	antimicrobial	skin protectant	IIISE	IIISE	pending
	antimicrobial I	antimicrobial	health care personnel handwash	IIISE	IIISE	pending

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<b>polycarbophil</b>					
laxative	antidiarrheal	antidiarrheal	I	I	310.545(a)(3)(ii)
laxative	laxative	bulk laxative	I	I	pending
<b>polycarbophil, calcium</b>					
laxative	antidiarrheal	antidiarrheal	n/a	I	310.545(a)(3)(ii)
laxative	laxative	bulk laxative	n/a	n/a	n/a
<b>polydimethylsiloxane and poloxamer</b>					
====	gingivitis/plaque	antiplaque/gingivitis	n/a	IIIIE	pending
<b>polyethylene glycol 300</b>					
ophthalmic	ophthalmic	demulcent	I	I	349.12(d)(2)
<b>polyethylene glycol 400</b>					
ophthalmic	ophthalmic	demulcent	I	I	349.12(d)(3)
<b>polyethylene glycol 6000</b>					
ophthalmic	ophthalmic	demulcent	n/a	IIIIE	310.545(a)(21)(iv)
<b>polymyxin b sulfate</b>					
antimicrobial II	antibiotic	skin wound protectant	I	defer	n/a
antimicrobial II	antibiotic	first aid antibiotic	IIIIE	I	333.120 [combos]
antimicrobial II	antibiotic	skin wound antibiotic	I	defer	n/a

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<b>polyoxyethylene laurate</b>						
miscellaneous external	external analgesic		astringent	I	n/a	n/a
miscellaneous external	skin protectant		astringent	I	I	310.545(a)(18)(ii)
<b>polyoxyethylene monolaurate [see polyoxyethylene laurate]</b>						
=====	=====		=====	=====	=====	=====
<b>polysorbate 20</b>						
miscellaneous external	hair growth/loss		hair grower	n/a	I	310.527(a)
<b>polysorbate 60</b>						
miscellaneous external	hair growth/loss		hair grower	n/a	I	310.527(a)
<b>polysorbate 80</b>						
ophthalmic	ophthalmic		demulcent	I	I	349.12(d)(4)
<b>polyvinyl alcohol</b>						
ophthalmic	ophthalmic		demulcent	I	I	349.12(e)
<b>polyvinylpyrrolidone [see povidone]</b>						
=====	=====		=====	=====	=====	=====
<b>potassium acetate</b>						
miscellaneous internal	menstrual/diuretic		diuretic	n/a	I	310.545(a)(24)(i)
<b>potassium alum</b> [see alum, potassium]						
=====	=====		=====	=====	=====	=====

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<b>potassium aluminum sulfate</b> [see alum, potassium]	=====	=====	=====	=====	=====	=====
<b>potassium bicarbonate</b>						
antacid	antacid		antacid	n/a	n/a	331.11(j)(1)
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
<b>potassium bromide</b>						
sedative	nighttime sleep aid		sleep aid	IISE	IISE	[54 FR 6826]
sedative	daytime sedative		sedative	IIS	IISE	310.519(a)
<b>potassium carbonate</b>						
antacid	antacid		antacid	n/a	n/a	331.11(j)(1)
laxative	antidiarrheal		antidiarrheal	IIE	IIE	310.545(a)(3)(ii)
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
<b>potassium chlorate</b>						
oral cavity	oral health care		antimicrobial	IISE	IISE	pending
<b>potassium citrate</b>						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
<b>potassium extract</b>						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)

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<b>potassium ferrocyanide</b>						
	miscellaneous external	external analgesic	astringent	IISE	n/a	pending
	miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
<b>potassium guaiacolsulfonate</b>						
cough/cold		cough/cold (expectorant)	expectorant	IIIIE	IIIIE	310.545(a)(6)(iii)
<b>potassium iodide</b>						
cough/cold		cough/cold (expectorant)	expectorant	IIS	IISE	310.545(a)(6)(iii)
oral cavity		oral health care	expectorant	IIS	IIS	310.545(a)(6)(iii)
<b>potassium nitrate</b>						
dental		relief of oral discomfort	tooth desensitizer	IIIIE	I	pending
miscellaneous internal		menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
<b>potassium sorbate</b>						
contraceptive/vaginal		vaginal	minor irritations	I	withdraw	n/a
<b>povidone</b>						
miscellaneous external		external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
miscellaneous external		skin protectant	poison ivy/oak/sumac	defer	IIE	310.545(a)(18)(vi)(A)
ophthalmic		ophthalmic	demulcent	I	I	349.12(f)
<b>povidone silver nitrate</b>						
miscellaneous internal		smoking deterrent	smoking deterrent	n/a	n/a	310.544(d)

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<b>povidone vinylacetate copolymers</b>						
	miscellaneous external	skin protectant	poison ivy/oak/sumac	n/a	n/a	310.545(a)(18)(vi)(A)
<b>povidone-iodine</b>						
antimicrobial I	antimicrobial	antiseptic	n/a	I	pending	
antimicrobial I	antimicrobial	surgical hand scrub	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	antimicrobial soap	n/a	IIISE	pending	
antimicrobial I	antimicrobial	skin protectant	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	skin wound cleanser	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	preoperative skin prep	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	skin antiseptic	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	health care personnel handwash	IIISE	IIISE	pending	
antimicrobial II	acne	acne	IIIIE	IIIIE	310.545(a)(1)	
antimicrobial II	antifungal	antifungal	IIIIE	I	333.210(d)	
contraceptive/vaginal	vaginal	minor irritations	I	withdraw	n/a	
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIIIE	IIIIE	310.545(a)(7)	
oral cavity	oral health care	antimicrobial	IIISE	IIISE	pending	
<b>povidone-iodine complex [see povidone-iodine]</b>						
=====	=====	=====	=====	=====	=====	=====

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<b>Review Panel</b>	<b>Report</b>					
<b>pramoxine hydrochloride</b>						
=====	external analgesic		poison ivy/oak/sumac	n/a	I	pending
hemorrhoidal	anorectal		anesthetic (external)	I	I	346.10(g)
hemorrhoidal	anorectal		anesthetic (intrarectal)	III	III	[55 FR 1779]
miscellaneous external antifungal			diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external antimicrobial			diaper rash	defer	n/a	pending
miscellaneous external external analgesic			diaper rash	defer	I	310.545(a)(10)(iv)
miscellaneous external external analgesic			fever blister (topical)	defer	I	pending
miscellaneous external skin protectant			diaper rash	defer	n/a	pending
topical analgesic	external analgesic		analgesic/anesthetic	I	I	pending
<b>pregnenolone</b>						
miscellaneous external hormone			hormone	I	I	310.530(a)
<b>pregnenolone acetate</b>						
miscellaneous external hormone			hormone	I	I	310.530(a)
<b>progesterone</b>						
miscellaneous external hormone			hormone	I	I	310.530(a)
<b>prolase</b>						
miscellaneous internal digestive aid			digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)

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<b>promethazine hydrochloride</b>						
cough/cold		cough/cold (antihistamine)	antihistamine	I	IIIS	[57 FR 58373]
<b>propionic acid</b>						
antimicrobial II		antifungal	antifungal	IIIIE	IIIIE	310.545(a)(22)(ii)
<b>propyl benzoate</b>						
miscellaneous external	skin protectant		fever blister (topical)	defer	n/a	n/a
<b>propyl p-benzoate</b>						
miscellaneous external	external analgesic		fever blister (topical)	defer	n/a	n/a
<b>propylene glycol</b>						
miscellaneous external	pediculicide		pediculicide	IIISE	IIISE	310.545(a)(25)(i)
ophthalmic	ophthalmic		demulcent	I	I	349.12(d)(5)
miscellaneous external	hair growth/loss		hair grower	IIISE	n/a	310.527(a)
<b>propylhexidrine</b>						
cough/cold		cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant))	I	I	341.20(b)(9)
<b>propylparaben</b>						
antimicrobial II		antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)
<b>protease</b>						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)

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<b>protein</b>					
miscellaneous external	hair growth/loss	hair grower	IISE	n/a	310.527(a)
<b>protein hydrolysate</b>					
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant	diaper rash	defer	IISE	310.545(a)(18)(iii)
<b>proteins [see protein]</b>					
=====	=====	=====	=====	=====	=====
<b>prune concentrate dehydrate</b>					
laxative	laxative	stimulant laxative	IIIIE	IIIIE	310.545(a)(12)(iv)(A)
<b>prune powder</b>					
laxative	laxative	stimulant laxative	IIIIE	IIIIE	310.545(a)(12)(iv)(A)
<b>pseudoephedrine sulfate</b>					
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (oral)	I	I	341.20(a)(3)
<b>pseudoephedrine hydrochloride</b>					
cough/cold	cough/cold (bronchodilator)	bronchodilator	IIIE	IIIE	310.545(a)(6)(iv)(A)
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (oral)	I	I	341.20(a)(2)

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<b>pseudoephedrine sulfate</b>						
cough/cold	cough/cold (bronchodilator)		bronchodilator	IIE	IIE	310.545(a)(6)(iv)(A)
<b>psyllium [see plantago seed]</b>						
=====	=====		=====	=====	=====	=====
<b>psyllium husk</b>						
laxative	laxative		bulk laxative	I	I	pending
<b>pyrantel pamoate</b>						
miscellaneous internal	antihelmintic		anthelmintic	I	I	357.110
<b>pyrethrins [see pyrethrum extract]</b>						
=====	=====		=====	=====	=====	=====
<b>pyrethrum extract (aerosol) with piperonyl butoxide</b>						
=====	pediculicide		pediculicide	n/a	n/a	310.545(a)(25)(ii)
<b>pyrethrum extract (nonaerosol) with piperonyl butoxide</b>						
miscellaneous external	pediculicide		pediculicide	I	I	358.610
<b>pyridoxine hydrochloride</b>						
miscellaneous external	external analgesic		fever blister (topical)	defer	DEF	pending
miscellaneous external	skin protectant		fever blister (topical)	defer	IISE	310.545(a)(18)(iv)
miscellaneous internal	menstrual/diuretic		premenstrual/menstrual period	IIIIE	IIIIE	pending
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)

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<b>Review Panel</b>	<b>Report</b>					
<b>pyrilamine maleate</b>						
antimicrobial II	acne		acne	IIE	IIE	310.545(a)(1)
cough/cold	cough/cold (antihistamine)		antihistamine	I	I	341.12(k)
internal analgesic	internal analgesic		analgesic adjuvant	IIIIE	IIIIE	310.545(a)(23)(i)
internal analgesic	internal analgesic		antipyretic adjuvant	IIIIE	IIIIE	310.545(a)(23)(i)
internal analgesic	internal analgesic		antirheumatic adjuvant	IIIIE	n/a	310.545(a)(23)(i)
miscellaneous external	external analgesic		insect bite/sting	IIISE	IIISE	310.545(a)(10)(vi)
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	IIISE	310.545(a)(10)(vii)
miscellaneous external	skin protectant		insect bite/sting	IIISE	IIISE	310.545(a)(18)(v)(A)
miscellaneous external	skin protectant		poison ivy/oak/sumac	n/a	IIISE	pending
miscellaneous internal	menstrual/diuretic		antihistamine	I	IIISE	pending
oral cavity	oral health care		analgesic/anesthetic	IIE	IIE	310.545(a)(14)
sedative	nighttime sleep aid		sleep aid	IIISE	IIISE	[54 FR 6826]
sedative	daytime sedative		sedative	IIISE	IIISE	310.519(a)
<b>pyrithione zinc</b>						
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff		I	I	358.710(a)(2)
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff		I	I	358.710(a)(3)
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	seborrheic dermatitis		I	I	358.710(b)(3)
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	seborrheic dermatitis		I	I	358.710(b)(2)

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<b>quinine</b>						
	internal analgesic	internal analgesic	analgesic	IIS	IIS	310.545(a)(23)(i)
	internal analgesic	internal analgesic	antipyretic	IIS	IIS	310.545(a)(23)(i)
	internal analgesic	internal analgesic	antirheumatic	IISE	not OTC	310.545(a)(23)(i)
<b>quinine ascorbate</b>						
	miscellaneous internal	smoking deterrent	smoking deterrent	IIE	IIE	310.544(d)
<b>quinine sulfate</b>						
	miscellaneous internal	leg muscle cramp	nocturnal leg muscle cramps	IIISE	IIISE	310.546
<b>racemethionine</b>						
	miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
	miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
	miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
	miscellaneous external	skin protectant	diaper rash	defer	IIISE	310.545(a)(18)(iii)
<b>racephedrine hydrochloride</b>						
cough/cold		cough/cold (bronchodilator)	bronchodilator	I	I	341.16(f)
cough/cold		cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	I	I	310.545(a)(6)(ii)(B)
cough/cold		cough/cold (nasal decongestant)	nasal decongestant (oral)	IIIIE	IIIIE	310.545(a)(6)(ii)(B)
<b>racepinephrine hydrochloride</b>						
cough/cold		cough/cold (bronchodilator)	bronchodilator	n/a	n/a	341.16(g)

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<b>red petrolatum</b> [see petrolatum, red]	====	====	====	====	====	====
<b>released carbon dioxide</b> [see carbon dioxide, released]	====	====	====	====	====	====
<b>reosote</b>						
	====	skin protectant	poison ivy/oak/sumac	n/a	I <sup>SE</sup>	310.545(a)(18)(vi)(A)
dental		relief of oral discomfort	toothache relief	II <sup>SE</sup>	II <sup>SE</sup>	pending
<b>resorcinol</b>						
	====	external analgesic	poison ivy/oak/sumac	n/a	I	pending
	====	n/a	dandruff/seborrheic dermatitis/psoriasis	n/a	n/a	310.545(a)(7)
antimicrobial II		acne	acne	II <sup>E</sup>	II <sup>E</sup>	310.545(a)(1)
antimicrobial II		antifungal	antifungal	II <sup>SE</sup>	II <sup>SE</sup>	310.545(a)(22)(ii)
hemorrhoidal		anorectal	antiseptic (intrarectal)	II <sup>SE</sup>	II <sup>SE</sup>	310.545(a)(26)(ii)
hemorrhoidal		anorectal	keratolytic (external)	I	I	346.20(a)
hemorrhoidal		anorectal	keratolytic (intrarectal)	II <sup>SE</sup>	II <sup>SE</sup>	346.20(a)
hemorrhoidal		anorectal	antiseptic (external)	II <sup>SE</sup>	II <sup>SE</sup>	310.545(a)(26)(ii)
miscellaneous external		antifungal	diaper rash	defer	II <sup>SE</sup>	310.545(a)(22)(ii)
miscellaneous external		antimicrobial	diaper rash	defer	II <sup>SE</sup>	pending
miscellaneous external		dandruff/seborrheic dermatitis/psoriasis	psoriasis	II <sup>E</sup>	II <sup>E</sup>	[56 FR 63567]

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		miscellaneous external	external analgesic	diaper rash	defer	IISE	310.545(a)(10)(iv)
		miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
		miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending
	topical analgesic		external analgesic	analgesic/anesthetic	I	I	pending
<b>resorcinol monoacetate</b>							
	antimicrobial II		acne	acne	IIE	IIE	310.545(a)(1)
<b>rhubarb fluidextract</b>							
	laxative		antidiarrheal	antidiarrheal	IISE	IISE	310.545(a)(3)(ii)
	miscellaneous internal		digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
<b>rhubarb, chinese</b>							
	laxative		laxative	stimulant laxative	IIISE	IIISE	310.545(a)(12)(iv)(A)
<b>riboflavin</b>							
	miscellaneous internal		menstrual/diuretic	premenstrual/menstrual period	n/a	IISE	310.545(a)(24)(i)
	miscellaneous internal		weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>rice polishings</b>							
	miscellaneous internal		weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>rose petals, infusion of</b>							
	ophthalmic		ophthalmic	astringent	IIIIE	IIIE	310.545(a)(21)(iii)

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<b>rosin</b>						
		miscellaneous external boil treatment	boil treatment	IISE	IISE	310.531(a)
<b>rosin cerate</b>						
		miscellaneous external boil treatment	boil treatment	IISE	IISE	310.531(a)
<b>sabadilla alkaloids</b>						
		miscellaneous external pediculicide	pediculicide	IISE	IISE	310.545(a)(25)(i)
<b>sabel, liposterolic extract of</b>						
		miscellaneous internal benign prostatic hypertrophy	benign prostatic hypertrophy	n/a	n/a	310.532(a)
<b>saccharin</b>						
		miscellaneous internal weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>sage oil</b>						
		miscellaneous external skin protectant	astringent	n/a	IISE	310.545(a)(18)(ii)
<b>salicyl alcohol</b>						
oral cavity		oral health care	analgesic/anesthetic	I	I	pending
<b>salicylamide</b>						
====		external analgesic	poison ivy/oak/sumac	n/a	IIIE	310.545(a)(10)(vii)
internal analgesic		internal analgesic	analgesic adjuvant	IIISE	IIISE	pending
internal analgesic		internal analgesic	analgesic	IIISE	IIISE	pending
internal analgesic		internal analgesic	antipyretic adjuvant	IIISE	IIISE	pending

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	internal analgesic	internal analgesic	antipyretic	IIISE	IIISE	pending
	internal analgesic	internal analgesic	antirheumatic adjuvant	IIISE	n/a	n/a
	internal analgesic	internal analgesic	antirheumatic	IISE	not OTC	n/a
miscellaneous external	external analgesic		fever blister (topical)	defer	IIIIE	310.545(a)(10)(v)
miscellaneous internal	menstrual/diuretic		analgesic	IIISE	IIISE	pending
sedative	nighttime sleep aid		sleep aid	IIE	IIE	[54 FR 6826]
sedative	daytime sedative		sedative	IIE	IISE	310.519(a)
topical analgesic	external analgesic		analgesic/anesthetic	IIIIE	IIIIE	310.545(a)(10)(i)
<b>salicylic acid</b>						
antimicrobial II	acne		acne	IIIIE	I	333.310(c)
antimicrobial II	antifungal		antifungal	IIIIE	IIIIE	310.545(a)(22)(ii)
antimicrobial II	acne		acne	IISE	IISE	310.545(a)(1)
miscellaneous external	antifungal		diaper rash	defer	IISE	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis		dandruff	I	I	358.710(a)(4)
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
miscellaneous external	skin protectant		diaper rash	defer	n/a	pending
miscellaneous external	skin protectant		poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)

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	miscellaneous external	corn/callus remover	corn/callus remover	I	I	358.510(a)
	miscellaneous external	wart remover	wart remover	I	IISE	358.110(a)
	miscellaneous external	wart remover	wart remover	I	I	358.110(b)
	miscellaneous external	wart remover	wart remover	I	I	358.110(c)
	miscellaneous external	corn/callus remover	corn/callus remover	I	I	358.510 (b)
	miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	seborrheic dermatitis	I	I	358.710(b)(4)
	miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	psoriasis	I	I	358.710(c)(2)
<b>salsalate</b>						
	internal analgesic	internal analgesic	analgesic	IISE	IISE	310.545(a)(23)(i)
	internal analgesic	internal analgesic	antipyretic	IISE	IISE	310.545(a)(23)(i)
	internal analgesic	internal analgesic	antirheumatic	IISE	not OTC	310.545(a)(23)(i)
<b>sanguinaria extract</b>						
====		gingivitis/plaque	gingivitis/antiplaque	n/a	III	pending
<b>sarsaparrilla</b>						
	miscellaneous internal	aphrodisiac	aphrodisiac	IISE	IISE	310.528(a)
<b>sassafras oil</b>						
	miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)
<b>saw palmetto</b>						
	miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)

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<b>scopolamine aminoxide hydrobromide</b>						
sedative		nighttime sleep aid	sleep aid	IISE	IIS	[54 FR 6826]
sedative		daytime sedative	sedative	IISE	IISE	310.519(a)
<b>scopolamine hydrobromide</b>						
laxative		antidiarrheal	antidiarrheal	IIE	IIE	310.545(a)(3)(i)
laxative		antiemetic	antiemetic	n/a	IIIIE	[52 FR 15891]
sedative		nighttime sleep aid	sleep aid	IISE	IIS	[54 FR 6826]
sedative		daytime sedative	sedative	IISE	IISE	310.519(a)
<b>sea kelp [see kelp]</b>						
====	====	====	====	====	====	====
<b>sea minerals</b>						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
<b>selenium sulfide</b>						
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff		I	I	358.710(a)(5)
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	seborrheic dermatitis		I	I	358.710(b)(5)
<b>selenium sulfide, micronized</b>						
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff		n/a	I	358.710(a)(6)
<b>senecio aureus</b>						
miscellaneous internal	menstrual/diuretic		dysmenorrhea	IISE	IISE	310.545(a)(24)(i)

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<b>senna</b> miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(8)(ii)
<b>senna fluidextract</b> laxative	laxative	stimulant laxative	I	I/IIIS	pending
<b>senna pod concentrate</b> laxative	laxative	stimulant laxative	I	I/IIIS	pending
<b>senna syrup</b> laxative	laxative	stimulant laxative	I	I/IIIS	pending
<b>sennosides a &amp; b [see sennosides]</b> ====	====	====	====	====	====
<b>sennosides a and b</b> laxative	laxative	stimulant laxative	I	I/IIIS	pending
<b>sesame oil</b> miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	pending
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	pending
<b>sesame seed</b> miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>shark liver oil</b> ====	insect bite/sting	insect bite/sting	n/a	n/a	310.545(a)(18)(v)(B)

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<b>Review Panel</b>	<b>Report</b>					
====	poison ivy/oak/sumac		poison ivy/oak/sumac	n/a	n/a	310.545(a)(18)(vi)(B)
====	skin protectant		fever blister (topical)	n/a	I	pending
hemorrhoidal	anorectal		wound healing agent (intrarectal)	IIIIE	IIIIE	310.545(a)(26)(x)
hemorrhoidal	anorectal		protectant (intrarectal)	I	I	346.14(b)(3)
hemorrhoidal	anorectal		wound healing agent (external)	IIIIE	IIIIE	310.545(a)(26)(x)
hemorrhoidal	anorectal		protectant (external)	I	I	346.14(b)(3)
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		protectant	I	I	pending
miscellaneous external	skin protectant		diaper rash	defer	IIISE	pending
topical analgesic	skin protectant		skin protectant	I	I	310.545(a)(18)(i)(B)
<b>silicone</b>						
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		diaper rash	defer	n/a	pending
<b>silver acetate</b>						
miscellaneous internal	smoking deterrent		smoking deterrent	IIIIE	IIIIE	310.544(d)

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<b>silver nitrate</b>						
	miscellaneous external	external analgesic	astringent	I	n/a	n/a
	miscellaneous external	skin protectant	astringent	I	I	310.545(a)(18)(ii)
	miscellaneous internal	smoking deterrent	smoking deterrent	I	I	310.544(d)
<b>silver protein, mild</b>						
ophthalmic	ophthalmic		anti-infective	III	III	310.545(a)(21)(ii)
<b>simethicone</b>						
antacid	antacid		antacid	III	II	[39 FR 19873]
antacid	antiflatulent		antiflatulent	III	I	332.10
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	I	310.545(a)(10)(vii)
miscellaneous external	skin protectant		poison ivy/oak/sumac	defer	I	310.545(a)(18)(vi)(A)
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	III	III	[58 FR 54454]
miscellaneous internal	digestive aid		digestive aid (ippuad)	III	III	[58 FR 54454]
<b>sodium</b>						
miscellaneous internal	weight control		anorectic	I	I	310.545(a)(20)
<b>sodium 3, 4-dimethylphenyl-glyoxylate</b>						
topical analgesic	sunscreen		sunscreen	I	I	[64 FR 27682]
<b>sodium acetylsalicylate</b>						
miscellaneous internal	overindulgence in alcohol/food		overindulgence remedies (hangover)	I	I	pending

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<b>sodium aluminum chlorohydroxy lactate (aerosol)</b>						
antiperspirant	antiperspirant	antiperspirant		IIISE	IIISE	310.545(a)(4)
<b>sodium aluminum chlorohydroxy lactate (nonaerosol)</b>						
antiperspirant	antiperspirant	antiperspirant		IIIIE	IIIE	310.545(a)(4)
<b>sodium aminobenzoate</b>						
internal analgesic	internal analgesic	analgesic adjuvant		IISE	IISE	310.545(a)(23)(i)
internal analgesic	internal analgesic	antipyretic adjuvant		IISE	IISE	310.545(a)(23)(i)
internal analgesic	internal analgesic	antirheumatic adjuvant		IISE	n/a	310.545(a)(23)(i)
<b>sodium benzoate</b>						
miscellaneous internal	menstrual/diuretic	diuretic		n/a	IIISE	310.545(a)(24)(i)
<b>sodium bicarbonate</b>						
====	gingivitis/plaque	gingivitis/antiplaque		n/a	IIIE	pending
antacid	antacid	antacid		I	I	331.11(k)(1)
contraceptive/vaginal	vaginal	alters vaginal pH		IIIE	withdraw	n/a
dental	anticaries	anticavity agent		IIE	IIE	[60 FR 52504]
internal analgesic	internal analgesic	corrective		I	n/a	n/a
miscellaneous external	antifungal	diaper rash		defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial	diaper rash		defer	n/a	pending
miscellaneous external	external analgesic	diaper rash		defer	n/a	310.545(a)(10)(iv)

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<b>Review Panel</b>	<b>Report</b>				
miscellaneous external	external analgesic	insect bite/sting	IISE	n/a	n/a
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	n/a	n/a
miscellaneous external	skin protectant	diaper rash	defer	IISE	pending
miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	pending
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	I	pending
miscellaneous internal	digestive aid	digestive aid (ippuad)	IIIIE	IIIIE	310.545(a)(8)(i)
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	IIIIE	IIIIE	310.545(a)(8)(i)
miscellaneous internal	weight control	anorectic	IIIIE	IISE	310.545(a)(20)
oral cavity	oral health care	debriding agent	I	I	pending
topical analgesic	skin protectant	skin protectant	I	I	347.10(o)
<b>sodium borate</b>					
antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)
antimicrobial II	antifungal	antifungal	IIIIE	IIIIE	310.545(a)(22)(ii)
contraceptive/vaginal	vaginal	lowers surface tension mucolytic effects	IIISE	withdraw	n/a
contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw	n/a
contraceptive/vaginal	vaginal	alters vaginal pH	IIISE	withdraw	n/a
contraceptive/vaginal	vaginal	astringent	IIISE	withdraw	n/a
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIE	IIE	310.545(a)(7)
miscellaneous external	external analgesic	astringent	n/a	n/a	n/a

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<b>Review Panel</b>	<b>Report</b>				
miscellaneous external	external analgesic	insect bite/sting	IISE	IISE	310.545(a)(10)(vi)
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	310.545(a)(18)(v)(A)
oral cavity	oral health care	debriding agent	IISE	IISE	pending
<b>sodium borate monohydrate</b>					
dental	oral mucosal injury	skin wound cleanser	IISE	IISE	pending
<b>sodium bromide</b>					
sedative	nighttime sleep aid	sleep aid	IISE	IISE	[54 FR 6826]
sedative	daytime sedative	sedative	IIS	IISE	310.519(a)
<b>sodium caprylate</b>					
antimicrobial II	antifungal	antifungal	IIIIE	IIIIE	310.545(a)(22)(ii)
oral cavity	oral health care	antimicrobial	IIIIE	IIIIE	pending
<b>sodium carbonate</b>					
antacid	antacid	antacid	I	I	331.11(k)(1)
contraceptive/vaginal	vaginal	alters vaginal pH	IIISE	withdraw n/a	
internal analgesic	internal analgesic	corrective	I	n/a	n/a
<b>sodium caseinate</b>					
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)

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<b>Review Panel</b>	<b>Report</b>					
<b>sodium chloride</b>						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
ophthalmic	ophthalmic		hypertonic agent	I	I	349.16
<b>sodium citrate</b>						
cough/cold	cough/cold (expectorant)		expectorant	IIIIE	IIIIE	310.545(a)(6)(iii)
dental	relief of oral discomfort		tooth desensitizer (in combination only)	IIIIE	IIIIE	pending
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	IIIIE	IIIIE	310.545(a)(8)(i)
miscellaneous internal	digestive aid		digestive aid (ippuad)	IIIIE	IIIIE	310.545(a)(8)(i)
<b>sodium citrate in solution</b>						
miscellaneous internal	overindulgence in alcohol/food		overindulgence remedies (hangover)	I	I	pending
miscellaneous internal	overindulgence in alcohol/food		overindulgence remedies (hangover)	I	I	pending
<b>sodium diacetate</b>						
miscellaneous external	external analgesic		astringent	IISE	n/a	n/a
miscellaneous external	skin protectant		astringent	IISE	IISE	310.545(a)(18)(ii)
<b>sodium dichromate</b>						
oral cavity	oral health care		antimicrobial	IIS	IISE	pending
<b>sodium dihydrogen phosphate</b> [see sodium phosphate, monobasic]						
=====	=====		=====	=====	=====	=====

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<b>sodium fluoride</b>						
dental		anticaries	anticavity dentrifrice	I	I	355.10(a)(2)
dental		anticaries	anticavity dental rinse	I	I	355.10(a)(3)(iv)
dental		anticaries	anticavity dental rinse	I	I	355.10(a)(3)(v)
dental		anticaries	anticavity dentrifrice	I	I	355.10(a)(1)
dental		anticaries	anticavity dental rinse	I	I	355.10(a)(3)(iii)
dental		relief of oral discomfort	tooth desensitizer (in combination only)	IISE	IISE	pending
dental		relief of oral discomfort	tooth desensitizer	IIIIE	IIIIE	pending
<b>sodium lactate</b>						
contraceptive/vaginal		vaginal	alters vaginal pH	IIIIE		withdraw n/a
<b>sodium lauryl sulfate</b>						
contraceptive/vaginal		vaginal	lowers surface tension mucolytic effects	I		withdraw n/a
<b>sodium monofluorophosphate</b>						
dental		anticaries	anticavity dentrifrice	I	I	355.10(b)(1)
dental		anticaries	anticavity dental rinse	IIS	IIS	310.545(a)(2)(i)
dental		relief of oral discomfort	tooth desensitizer	IIIIE	IIIIE	pending
dental		anticaries	anticavity dentrifrice	I	I	355.10(b)(2)
<b>sodium nitrate</b>						
miscellaneous internal		menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)

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<b>sodium oleate</b>					
laxative	laxative	stimulant laxative	IIIIE	IIIIE	310.545(a)(12)(iv)(A)
<b>sodium perborate</b>					
contraceptive/vaginal	vaginal	alters vaginal pH	IIISE	withdraw n/a	
contraceptive/vaginal	vaginal	astringent	IIISE	withdraw n/a	
contraceptive/vaginal	vaginal	lowers surface tension mucolytic effects	IIISE	withdraw n/a	
contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw n/a	
oral cavity	oral health care	debriding agent	IIISE	IIISE	pending
<b>sodium perborate monohydrate</b>					
dental	oral health care	wound cleanser	IIE	I	pending
<b>sodium phosphate [see sodium phosphate, dibasic]</b>					
=====	=====	=====	=====	=====	=====
<b>sodium phosphate, dibasic</b>					
dental	anticaries	anticavity agent	IIE	IIE	310.545(a)(2)(ii)
laxative	laxative	saline laxative	I	I	pending
<b>sodium phosphate, dibasic anhydrous reagent [see sodium phosphate, dibasic]</b>					
=====	=====	=====	=====	=====	=====
<b>sodium phosphate, monobasic</b>					
dental	anticaries	anticavity agent	IIE	IIE	310.545(a)(2)(ii)

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	laxative	laxative	saline laxative	I	I	pending
<b>sodium potassium tartrate</b>						
	antacid	antacid	antacid	I	I	331.11(j)(2) 331.11(k)(2)
<b>sodium potassium tartrate [see potassium sodium tartrate]</b>						
=====	=====	=====	=====	=====	=====	=====
<b>sodium propionate</b>						
antimicrobial II	antifungal		antifungal	IIIIE	IIIIE	310.545(a)(22)(ii)
contraceptive/vaginal	vaginal		minor irritations	I	withdraw n/a	
miscellaneous external	antifungal		diaper rash	defer	IIISE	310.545(a)(22)(ii)
miscellaneous external	antimicrobial		diaper rash	defer	IIISE	pending
<b>sodium salicylate</b>						
contraceptive/vaginal	vaginal		minor irritations	IIISE	withdraw n/a	
internal analgesic	internal analgesic		analgesic	I	I	pending
internal analgesic	internal analgesic		antipyretic	I	I	pending
internal analgesic	internal analgesic		antirheumatic	I	not OTC	n/a
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis		dandruff/seborrheic dermatitis/psoriasis	IIIIE	IIIIE	310.545(a)(7)
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
miscellaneous internal	menstrual/diuretic		analgesic	I	I	pending
miscellaneous internal	menstrual/diuretic		diuretic	IIIIE	IIIIE	310.545(a)(24)(i)

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	miscellaneous internal	overindulgence in alcohol/food	overindulgence remedies (hangover)	I	I	pending
<b>sodium salicylate acid phenolate</b>						
hemorrhoidal	anorectal	antiseptic (intrarectal)	IIE	IIE	310.545(a)(26)(ii)	
hemorrhoidal	anorectal	antiseptic (external)	IIE	IIE	310.545(a)(26)(ii)	
contraceptive/vaginal	vaginal	minor irritations	IIE	withdraw	n/a	
<b>sodium sulfide</b>						
miscellaneous external	ingrown toenail	ingrown toenail	n/a	I	538.310	
miscellaneous external	ingrown toenail	ingrown toenail	IIIIE	IIIIE	310.538(a) [removed 68 FR 24348]	
<b>sodium thiosulfate</b>						
antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)	
<b>sorbitan monostearate</b>						
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending	
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)	
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending	
<b>sorbitan sesquioleate</b>						
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	n/a	
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	n/a	

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<b>Review Panel</b>	<b>Report</b>					
<b>sorbitol</b>						
laxative	laxative		hyperosmotic laxative	I	I	pending
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	IIE	IIE	310.545(a)(8)(i)
miscellaneous internal	digestive aid		digestive aid (ippuad)	IIE	IIE	310.545(a)(8)(i)
oral cavity	oral health care		oral health care nonantimicrobial	n/a	n/a	310.545(a)(14)
<b>soyasterol</b>						
miscellaneous external	external analgesic		fever blister (topical)	defer	n/a	n/a
miscellaneous external	skin protectant		fever blister (topical)	defer	n/a	n/a
<b>soybean oil, hydrogenated</b>						
miscellaneous internal	cholecystokinetic		cholecystokinetic	n/a	n/a	357.210(b)
<b>soybean protein</b>						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
<b>soymeal</b>						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
<b>spermaceti</b>						
miscellaneous external	external analgesic		fever blister (topical)	defer	n/a	n/a
miscellaneous external	skin protectant		fever blister (topical)	defer	n/a	n/a
<b>squill</b>						
cough/cold	cough/cold (expectorant)		expectorant	IISE	IISE	310.545(a)(6)(iii)

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<b>squill extract</b>					
cough/cold	cough/cold (expectorant)	expectorant	IISE	IISE	310.545(a)(6)(iii)
<b>stannous fluoride</b>					
====	gingivitis/plaque	antiplaque/gingivitis	n/a	I	pending
dental	anticaries	anticavity dental gel	I	I	355.10(c)(2)
dental	anticaries	anticavity dentrifrice	I	I	355.10(c)(1)
dental	anticaries	anticavity dental rinse	I	I	355.10(c)(3)
dental	relief of oral discomfort	tooth desensitizer	IIIIE	IIIIE	pending
<b>stannous pyrophosphate and zinc citrate</b>					
====	gingivitis/plaque	antiplaque/gingivitis	n/a	IIIIE	pending
<b>stearyl alcohol</b>					
====	insect bite/sting	insect bite/sting	n/a	n/a	310.545(a)(18)(v)(B)
====	poison ivy/oak/sumac	poison ivy/oak/sumac	n/a	n/a	310.545(a)(18)(vi)(B)
====	skin protectant	Skin protectant	n/a	n/a	310.545(a)(18)(i)(B)
<b>stem bromelain</b>					
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
<b>strawberry</b>					
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)

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<b>strontium chloride</b>						
dental		relief of oral discomfort	tooth desensitizer (in combination only)	IISE	IISE	pending
dental		relief of oral discomfort	tooth desensitizer	IIIIE	IIIIE	pending
<b>strychnine</b>						
miscellaneous internal	aphrodisiac		aphrodisiac	IISE	IISE	310.528(a)
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
<b>sucrose</b>						
miscellaneous internal	menstrual/diuretic		diuretic	n/a	IISE	310.545(a)(24)(i)
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
<b>sucrose octaacetate</b>						
miscellaneous external	nailbiting/thumbsucking		nailbiting/thumbsucking deterrent	IIIIE	IIIIE	310.536(a)
<b>sugars</b>						
oral cavity	oral health care		oral health care nonantimicrobial	n/a	n/a	310.545(a)(14)
<b>sulfacetamide sodium</b>						
miscellaneous external	hair growth/loss		hair grower	n/a	n/a	310.527(a)
ophthalmic	ophthalmic		anti-infective	IIS	IIS	310.545(a)(21)(ii)
<b>sulfur</b>						
====	external analgesic		poison ivy/oak/sumac	n/a	IIE	310.545(a)(10)(vii)
====	skin protectant		wound healing agent	n/a	n/a	310.545(a)(18)(i)(A)

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Review Panel	Report					
antimicrobial II	acne		acne	I	I	333.310(d)
antimicrobial II	acne		acne	I	I	333.310(e)
miscellaneous external	boil treatment		boil treatment	n/a	IIISE	310.531(a)
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff		I	I	358.710(a)(7)
miscellaneous external	skin protectant	diaper rash		defer	IIISE	310.545(a)(18)(iii)
miscellaneous external	skin protectant	fever blister (topical)		defer	IIISE	310.545(a)(18)(iv)
topical analgesic	skin protectant	skin protectant		IIISE	IIISE	310.545(a)(18)(i)(A)
<b>sulfur (paraffinic hydrocarbons)</b>						
miscellaneous external	hair growth/loss		hair grower	n/a	IIE	310.527(a)
<b>sulfur, precipitated</b>						
hemorrhoidal	anorectal		keratolytic (external)	IIIIE	IIIIE	310.545(a)(26)(v)
hemorrhoidal	anorectal		keratolytic (intrarectal)	IIE	IIE	310.545(a)(26)(v)
<b>sulfur, sublimed</b>						
hemorrhoidal	anorectal		keratolytic (intrarectal)	IIE	IIE	310.545(a)(26)(v)
hemorrhoidal	anorectal		keratolytic (external)	IIIIE	IIIIE	310.545(a)(26)(v)
miscellaneous external	pediculicide		pediculicide	IIISE	IIISE	310.545(a)(25)(i)
<b>sulfurated oils of turpentine</b>						
miscellaneous internal	menstrual/diuretic		diuretic	n/a	IISE	310.545(a)(24)(i)

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<b>sulisobenzzone</b>						
topical analgesic	sunscreen		sunscreen	I	I	352.10(o)
<b>sweet spirits of nitre</b>						
miscellaneous external	sweet spirits of nitre		all indications	IISE	n/a	310.502(a)(12)
<b>syrup of pine tar [see pine tar syrup]</b>						
=====	=====		=====	=====	=====	=====
<b>talc</b>						
=====	antimicrobial		diaper rash	n/a	n/a	pending
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	external analgesic		astringent	IISE	n/a	n/a
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		astringent	IISE	IISE	310.545(a)(18)(ii)
miscellaneous external	skin protectant		diaper rash	defer	I	pending
<b>talcum powder</b>						
miscellaneous external	external analgesic		fever blister (topical)	defer	n/a	n/a
miscellaneous external	skin protectant		fever blister (topical)	defer	n/a	n/a
<b>tannic acid</b>						
=====	skin protectant		diaper rash	n/a	IISE	310.545(a)(18)(iii)
=====	skin protectant		wound healing agent	n/a	n/a	310.545(a)(18)(i)

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<b>Review Panel</b>	<b>Report</b>					
antimicrobial II	antifungal		antifungal	IIE	IIE	310.545(a)(22)(ii)
hemorrhoidal	anorectal		astringent (external)	IISE	IISE	310.545(a)(26)(iii)
hemorrhoidal	anorectal		anorectal (intrarectal)	IISE	IISE	310.545(a)(26)(iii)
miscellaneous external	external analgesic		fever blister (topical)	defer	IIISE	310.545(a)(10)(v)
miscellaneous external	external analgesic		insect bite/sting	n/a	IIIIE	pending
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	IIIIE	310.545(a)(10)(vii)
miscellaneous external	ingrown toenail		ingrown toenail	IIIIE	IIIIE	310.538(a)
miscellaneous external	ingrown toenail		astringent(external)	IIIIE	IIIIE	310.538(a)
miscellaneous external	skin protectant		fever blister (topical)	defer	IIISE	310.545(a)(18)(iv)
miscellaneous external	skin protectant		poison ivy/oak/sumac	defer	IIISE	310.545(a)(18)(vi)(A)
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(8)(ii)
topical analgesic	skin protectant		skin protectant	IISE	IISE	310.545(a)(18)(i)(A)
<b>tannic acid glycerite</b>						
miscellaneous external	external analgesic		astringent	IISE	n/a	n/a
miscellaneous external	skin protectant		astringent	IISE	IISE	310.545(a)(18)(ii)
<b>tar oil</b>						
miscellaneous external	hair growth/loss		hair grower	IISE	n/a	310.527(a)
<b>taraxacum officinale</b>						
miscellaneous external	menstrual/diuretic		dysmenorrhea	IIE	IIIE	310.545(a)(24)(i)

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<b>tartaric acid</b>						
antacid		antacid	antacid	I	I	331.11(m)
contraceptive/vaginal		vaginal	alters vaginal pH	IIIIE	withdraw n/a	
laxative		laxative	saline laxative	IIISE	IIISE	310.545(a)(12)(ii)
<b>terpin hydrate</b>						
cough/cold		cough/cold (expectorant)	expectorant	IIIIE	IIIIE	310.545(a)(6)(iii)
<b>terpin hydrate elixir</b>						
cough/cold		cough/cold (expectorant)	expectorant	IIIIE	IIIIE	310.545(a)(6)(iii)
<b>testosterone</b>						
miscellaneous internal		aphrodisiac	aphrodisiac	IIS	IIS	310.528(a)
<b>tetracaine</b>						
====		external analgesic	poison ivy/oak/sumac	n/a	I	pending
hemorrhoidal		anorectal	anesthetic (external)	IIIIE	I	346.10(h)
hemorrhoidal		anorectal	anesthetic (intrarectal)	IIIIE	IIIIE	[55 FR 1779]
miscellaneous external		antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external		antimicrobial	diaper rash	defer	n/a	pending
miscellaneous external		external analgesic	diaper rash	defer	IIS	310.545(a)(10)(iv)
miscellaneous external		external analgesic	fever blister (topical)	defer	I	pending
miscellaneous external		skin protectant	diaper rash	defer	n/a	pending

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oral cavity	oral health care		analgesic/anesthetic	IIS	IIS	310.545(a)(14)
topical analgesic	external analgesic		analgesic/anesthetic	I	I	pending
<b>tetracaine hydrochloride</b>						
====	external analgesic		poison ivy/oak/sumac	n/a	I	pending
antimicrobial II	acne		acne	IISE	IISE	310.545(a)(1)
hemorrhoidal	anorectal		anesthetic (external)	IIIIE	I	346.10(i)
hemorrhoidal	anorectal		anesthetic (intrarectal)	IIIIE	IIIIE	[55 FR 1779]
miscellaneous external	external analgesic		fever blister (topical)	defer	I	pending
miscellaneous external	hair growth/loss		hair grower	IIE	IIE	310.527(a)
oral cavity	oral health care		analgesic/anesthetic	IIS	IIS	310.545(a)(14)
topical analgesic	external analgesic		analgesic/anesthetic	I	I	pending
<b>tetracycline hydrochloride</b>						
antimicrobial II	antibiotic		first aid antibiotic	n/a	I	333.110(f)
antimicrobial II	antibiotic		skin wound antibiotic	IIIIE	defer	n/a
antimicrobial II	antibiotic		skin wound protectant	I	defer	n/a
<b>tetrahydrozoline hydrochloride</b>						
ophthalmic	ophthalmic		vasoconstrictor	I	I	349.18(d)
<b>thenyldiamine hydrochloride</b>						
cough/cold	cough/cold (antihistamine)		antihistamine	IIIIE	IIIIE	310.545(a)(6)(i)(A)&(B)

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	cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	III E	III E	[59 FR 43408]
<b>theobromine sodium salicylate</b>						
	miscellaneous internal	menstrual/diuretic	diuretic	III E	III E	310.545(a)(24)(i)
<b>theophylline</b>						
	miscellaneous internal	menstrual/diuretic	diuretic	III E	III E	310.545(a)(24)(i)
<b>theophylline (all combinations)</b>						
cough/cold		cough/cold (bronchodilator)	bronchodilator	n/a	n/a	310.545(a)(6)(iv)(B)
<b>theophylline anhydrous [see theophylline, anhydrous]</b>						
=====	=====	=====	=====	=====	=====	=====
<b>theophylline anhydrous [see theophylline]</b>						
=====	=====	=====	=====	=====	=====	=====
<b>theophylline calcium salicylate</b>						
cough/cold		cough/cold (bronchodilator)	bronchodilator	I	IIS	310.545(a)(6)(iv)(A)
<b>theophylline sodium glycinate</b>						
cough/cold		cough/cold (bronchodilator)	bronchodilator	I	IIS	310.545(a)(6)(iv)(A)
<b>theophylline, anhydrous</b>						
cough/cold		cough/cold (bronchodilator)	bronchodilator	I	IIS	310.545(a)(6)(iv)(A)
<b>thiamine</b>						
	miscellaneous internal	oral insect repellent	insect repellent	IIE	IIE	310.529(a)

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<b>thiamine hydrochloride</b>						
	miscellaneous external	hair growth/loss	hair grower	n/a	n/a	310.527(a)
	miscellaneous internal	menstrual/diuretic	menstrual	n/a	IISE	310.545(a)(24)(i)
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
sedative		nighttime sleep aid	sleep aid	IIE	IIE	[54 FR 6826]
sedative		daytime sedative	sedative	IIE	IISE	310.519(a)
<b>thiamine mononitrate</b>						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>thimerosal</b>						
	miscellaneous external	mercury	antiseptic	IISE	IISE	310.545(a)(27)(i)
	miscellaneous external	mercury	first aid antiseptic	n/a	IISE	310.545(a)(27)(i)
<b>thiocyanatoacetate</b>						
====		pediculicide	pediculicide	n/a	n/a	310.545(a)(25)(i)
<b>thonzylamine hydrochloride</b>						
cough/cold		cough/cold (antihistamine)	antihistamine	I	I	341.12(l)
<b>threonine</b>						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>thyme oil, white</b>						
	miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)

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	miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
	miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
	miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
<b>thymol</b>						
====		external analgesic	poison ivy/oak/sumac	n/a	IIIIE	310.545(a)(10)(vii)
antimicrobial II		acne	acne	IIIE	IIIIE	310.545(a)(1)
antimicrobial II		antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)
cough/cold		cough/cold (antihistamine)	antitussive (topical/inhalant)	IIIE	IIIIE	[52 FR 30055]
cough/cold		cough/cold (nasal decongestant)	nasal decongestant (inhalant room snrav <sup>y</sup> )	IIIE	IIIIE	310.545(a)(6)(ii)(A)
cough/cold		cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	IIIE	IIIIE	310.545(a)(6)(ii)(A)
cough/cold		cough/cold (nasal decongestant)	nasal decongestant (lozenge)	IIIE	IIIIE	310.545(a)(6)(ii)(A)
cough/cold		cough/cold (nasal decongestant)	nasal decongestant (mouthwash)	IIIE	IIIIE	310.545(a)(6)(ii)(A)
dental		relief of oral discomfort	toothache relief	IIIE	IIIIE	pending
dental		relief of oral discomfort	oral mucosal analgesic	IIIE	IIIIE	pending
miscellaneous external		boil treatment	boil treatment	IISE	IISE	310.531(a)
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIIE	IIIIE	310.545(a)(7)
miscellaneous external	external analgesic		astringent	IISE	n/a	n/a
miscellaneous external	external analgesic		fever blister (topical)	defer	IIISE	310.545(a)(10)(v)
miscellaneous external	skin protectant		astringent	IISE	IISE	310.545(a)(18)(ii)

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	miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	n/a
	miscellaneous internal	smoking deterrent	smoking deterrent	IIE	IIE	310.544(d)
oral cavity		oral health care	antimicrobial	IIIIE	IIIIE	pending
oral cavity		oral health care	analgesic/anesthetic	IIIIE	IIIIE	310.545(a)(14)
topical analgesic		external analgesic	analgesic/anesthetic	IIIIE	IIIIE	310.545(a)(10)(i)
<b>thymol iodide</b>						
dental		relief of oral discomfort	oral mucosal analgesic	IIIIE	IIIIE	pending
dental		relief of oral discomfort	toothache relief	IIIIE	IIIIE	pending
oral cavity		oral health care	antimicrobial	IIISE	IIISE	pending
<b>tincture of impatiens bi-flora</b> [see impatiens bi-flora tincture]						
=====	=====	=====	=====	=====	=====	=====
<b>tincture of iodine</b> [see iodine tincture]						
=====	=====	=====	=====	=====	=====	=====
<b>titanium dioxide</b>						
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	pending	
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	n/a	
topical analgesic	sunscreen	sunscreen	I	I	352.10(p)	
<b>tolindate</b>						
antimicrobial II	antifungal	antifungal	IISE	IISE	310.545(a)(22)(ii)	

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<b>tolnaftate</b>						
antimicrobial II	antifungal		antifungal	I	I	333.210(e)
<b>tolu</b>						
cough/cold	cough/cold (expectorant)		expectorant	IIIIE	IIIIE	310.545(a)(6)(iii)
<b>tolu balsam</b>						
cough/cold	cough/cold (expectorant)		expectorant	IIIIE	IIIIE	310.545(a)(6)(iii)
oral cavity	oral health care		antimicrobial	IIIIE	IIIIE	pending
oral cavity	oral health care		expectorant	IIIIE	n/a	310.545(a)(6)(iii)
<b>tolu balsam tincture</b>						
cough/cold	cough/cold (expectorant)		expectorant	IIIIE	IIIIE	310.545(a)(6)(iii)
<b>topical starch</b>						
====	skin protectant		poison ivy/oak/sumac	n/a	IIIIE	310.545(a)(18)(vi)(A)
hemorrhoidal	anorectal		protectant (external)	I	I	346.14(9)
hemorrhoidal	anorectal		protectant (intrarectal)	I	I	346.14(9)
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		astringent	IIISE	IIISE	pending
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		astringent	IIISE	IIISE	310.545(a)(18)(ii)

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	miscellaneous external	skin protectant	diaper rash	defer	I	pending
	miscellaneous external	skin protectant	fever blister (topical)	defer	IIISE	310.545(a)(18)(iv)
	topical analgesic	skin protectant	skin protectant	I	defer	347.10(q)
<b>triacetin</b>						
	antimicrobial II	antifungal	antifungal	IIIIE	IIIIE	310.545(a)(22)(ii)
<b>tribromosalan</b>						
	antimicrobial I	antimicrobial	antimicrobial	IIS	n/a	310.502(a)(5)
<b>tricalcium phosphate</b>						
	antacid	antacid	antacid	n/a	n/a	331.11(i)(3)
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>tricalcium phosphate</b> [see calcium phosphate, tribasic]						
====	====	====	====	====	====	====
<b>triclocarban</b>						
	antimicrobial I	antimicrobial	skin antiseptic	n/a	IIIIE	pending
	antimicrobial I	antimicrobial	skin wound cleanser	IISE	IIISE	pending
	antimicrobial I	antimicrobial	antimicrobial soap	IIISE	IIISE	pending
	antimicrobial I	antimicrobial	preoperative skin prep	IIISE	IISE	pending
	antimicrobial I	antimicrobial	surgical hand scrub	IIISE	IISE	pending
	antimicrobial I	antimicrobial	skin antiseptic	IIISE	IISE	pending

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	antimicrobial I	antimicrobial	skin protectant	IISE	IISE	pending
	antimicrobial I	antimicrobial	health care personnel handwash	IIISE	IIISE	pending
<b>triclosan</b>						
	antimicrobial I	antimicrobial	skin antiseptic	n/a	IIIIE	pending
	antimicrobial I	antimicrobial	antimicrobial soap	IIISE	IIISE	pending
	antimicrobial I	antimicrobial	preoperative skin prep	IIISE	IIISE	pending
	antimicrobial I	antimicrobial	surgical hand scrub	IIISE	IIISE	pending
	antimicrobial I	antimicrobial	skin wound cleanser	IIISE	IIISE	pending
	antimicrobial I	antimicrobial	skin antiseptic	IIISE	IIISE	pending
	antimicrobial I	antimicrobial	skin protectant	IIISE	IIISE	pending
	antimicrobial I	antimicrobial	health care personnel handwash	IIISE	IIISE	pending
miscellaneous external	antimicrobial	diaper rash	defer	IIISE	pending	
miscellaneous external	boil treatment	boil treatment	n/a	n/a	310.531(a)	
<b>trillium</b>						
miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)	
<b>tripelennamine hydrochloride</b>						
====	external analgesic	poison ivy/oak/sumac	n/a	I	pending	
cough/cold	cough/cold (antihistamine)	antihistamine	n/a	n/a	[57 FR 58373]	
miscellaneous external	external analgesic	fever blister (topical)	defer	IIIIE	310.545(a)(10)(v)	

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	topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending
<b>triple dye</b>						
antimicrobial I	antimicrobial		skin antiseptic	n/a	IIISE	pending
antimicrobial I	antimicrobial		antimicrobial soap	n/a	IIISE	pending
antimicrobial I	antimicrobial		preoperative skin prep	n/a	IIISE	pending
antimicrobial I	antimicrobial		surgical hand scrub	n/a	IIISE	pending
antimicrobial I	antimicrobial		skin antiseptic	IIISE	IIISE	pending
antimicrobial I	antimicrobial		skin protectant	n/a	IIISE	pending
antimicrobial I	antimicrobial		skin wound cleanser	n/a	IIISE	pending
antimicrobial I	antimicrobial		health care personnel handwash	n/a	IIISE	pending
<b>triprolidine hydrochloride</b>						
cough/cold	cough/cold (antihistamine)		antihistamine	n/a	I	341.12(m)
<b>triticum</b>						
miscellaneous internal	menstrual/diuretic		menstrual	n/a	IIISE	310.545(a)(24)(i)
miscellaneous internal	menstrual/diuretic		diuretic	n/a	IIISE	310.545(a)(24)(i)
<b>trolamine</b>						
miscellaneous external	external analgesic		insect bite/sting	IIIIE	IIISE	pending
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	n/a	pending
miscellaneous external	skin protectant		fever blister (topical)	defer	IIIIE	310.545(a)(18)(iv)(A)

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miscellaneous external	skin protectant		insect bite/sting	IIIIE	IIIIE	310.545(a)(18)(v)
miscellaneous external	skin protectant		poison ivy/oak/sumac	defer	IIIIE	310.545(a)(18)(vi)(A)
<b>trolamine salicylate</b>						
miscellaneous external	external analgesic		fever blister (topical)	defer	IIIIE	310.545(a)(10)(v)
miscellaneous external	external analgesic		insect bite/sting	n/a	IIIIE	310.545(a)(10)(vi)
miscellaneous external	external analgesic		poison ivy/oak/sumac	n/a	IIIIE	310.545(a)(10)(vii)
topical analgesic	external analgesic		analgesic/anesthetic	IIIIE	IIIIE	pending
topical analgesic	sunscreen		sunscreen	I	I	352.10(q)
<b>tryptophan</b>						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
<b>turpentine oil</b>						
cough/cold	cough/cold (antitussive)		antitussive (oral)	IISE	IISE	pending
cough/cold	cough/cold (antitussive)		antitussive (topical/inhalant)	IIIIE	IIIIE	[52 FR 30055]
cough/cold	cough/cold (expectorant)		expectorant (topical/inhalant)	IIIIE	IIIIE	310.545(a)(6)(iii)
cough/cold	cough/cold (expectorant)		expectorant (oral)	IISE	IISE	310.545(a)(6)(iii)
cough/cold	cough/cold (nasal decongestant)		nasal decongestant (oral)	IISE	IISE	310.545(a)(6)(ii)(A)
cough/cold	cough/cold (nasal decongestant)		nasal decongestant (topical/inhalant)	IIIIE	IIIIE	310.545(a)(6)(ii)(A)
topical analgesic	external analgesic		counterirritant	I	I	pending
miscellaneous external	external analgesic		fever blister (topical)	defer	IIIIE	310.545(a)(10)(v)

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	miscellaneous external	external analgesic	insect bite/sting	IISE	IISE	310.545(a)(10)(vi)
	miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
	miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	310.545(a)(18)(v)(A)
	miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
<b>turpentine oil, rectified</b>						
hemorrhoidal		anorectal	counterirritant (intrarectal)	IISE	IISE	310.545(a)(26)(iv)
hemorrhoidal		anorectal	counterirritant (external)	IISE	IISE	310.545(a)(26)(iv)
<b>turpentine, venice</b>						
miscellaneous internal	menstrual/diuretic		diuretic	n/a	IISE	310.545(a)(24)(i)
<b>tyrosine</b>						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
<b>undecoylum chlorideiodine complex [see undecoylum chloride iodine complex]</b>						
=====	=====	=====	=====	=====	=====	=====
<b>undecoylum chlorideiodine complex</b>						
antimicrobial I	antimicrobial		antimicrobial soap	n/a	IISE	pending
antimicrobial I	antimicrobial		skin wound cleanser	IIISE	IIISE	pending
antimicrobial I	antimicrobial		surgical hand scrub	IIISE	IIISE	pending
antimicrobial I	antimicrobial		skin protectant	IIISE	IIISE	pending
antimicrobial I	antimicrobial		skin antiseptic	IIISE	IIISE	pending

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	antimicrobial I	antimicrobial	preoperative skin prep	IIIE	IIIE	pending
	antimicrobial I	antimicrobial	health care personnel handwash	IIIIE	IIIIE	pending
<b>undecylenic acid</b>						
	antimicrobial II	antifungal	antifungal	I	I	333.210(f)
	miscellaneous external	antifungal	diaper rash	defer	IISE	310.545(a)(22)(i)
<b>undecylenic acid monoethanolamine sulfosuccinate sodium</b>						
	miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIIIE	IIIIE	310.545(a)(7)
<b>urea</b>						
	miscellaneous external	hair growth/loss	hair grower	n/a	IIE	310.527(a)
	miscellaneous external	ingrown toenail	ingrown toenail	IISE	IISE	310.538(a)
	miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
<b>uva ursi, extract</b>						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>valine</b>						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>vegetable</b>						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
<b>vegetable oil</b>						
	miscellaneous external	hair growth/loss	hair grower	IISE	n/a	310.527(a)

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<b>vitamin A</b>						
contraceptive/vaginal	vaginal		minor irritations	IIIIE	withdraw	n/a
hemorrhoidal	anorectal		wound healing agent (external)	IIIIE	IIIE	310.545(a)(26)(x)
hemorrhoidal	anorectal		wound healing agent (intrarectal)	IIIIE	IIIE	310.545(a)(26)(x)
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		diaper rash	defer	IIISE	pending
miscellaneous external	corn/callus remover		corn/callus remover	IIISE	IIISE	[55 FR 33261]
miscellaneous internal	weight control		anorectic	IIISE	IIISE	310.545(a)(20)
miscellaneous internal	weight control		anorectic	IIISE	IIISE	310.545(a)(20)
<b>vitamin A acetate</b>						
miscellaneous internal	weight control		anorectic	IIISE	IIISE	310.545(a)(20)
<b>vitamin A palmitate</b>						
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		diaper rash	defer	n/a	pending
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous internal	weight control		anorectic	IIISE	IIISE	310.545(a)(20)

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<b>vitamin B</b>						
	miscellaneous external	hair growth/loss	hair grower	n/a	IIE	310.527(a)
<b>vitamin D [see cholecalciferol]</b>	=====	=====	=====	=====	=====	=====
<b>vitamin D2 [see ergocalciferol]</b>	=====	=====	=====	=====	=====	=====
<b>vitamin E</b>						
antimicrobial II	acne		acne	IIE	IIE	310.545(a)(1)
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	hair growth/loss		hair grower	IIE	n/a	310.527(a)
miscellaneous external	skin protectant		diaper rash	defer	withdraw	n/a
miscellaneous internal	leg muscle cramp		nocturnal leg muscle cramps	n/a	IIISE	310.546
miscellaneous internal	weight control		anorectic	IIISE	IIISE	310.545(a)(20)
sedative	stimulant		stimulant	IIE	IIE	[39 FR 6104]
<b>vitamins</b>						
miscellaneous external	hair growth/loss		hair grower	IIISE	n/a	310.527(a)
miscellaneous internal	aphrodisiac		aphrodisiac	n/a	IIISE	310.528(a)

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<b>vitromersal</b>						
	miscellaneous external mercury		first aid antiseptic	n/a	IISE	310.545(a)(27)(i)
	miscellaneous external mercury		antiseptic	IISE	IISE	310.545(a)(27)(i)
<b>water and additives</b>						
====	ophthalmic		emergency first aid eyewash	n/a	I	pending
<b>water, purified</b>						
====	ophthalmic		eyewash	n/a	n/a	349.20
<b>wax, candelilla</b>						
	miscellaneous external external analgesic		fever blister (topical)	defer	n/a	n/a
	miscellaneous external skin protectant		fever blister (topical)	defer	n/a	n/a
<b>wax, carnauba</b>						
	miscellaneous external external analgesic		fever blister (topical)	defer	n/a	n/a
	miscellaneous external skin protectant		fever blister (topical)	defer	n/a	n/a
<b>wax, white</b>						
ophthalmic	ophthalmic		emollient	I	I	349.14(b)(6)
<b>wax, yellow</b>						
ophthalmic	ophthalmic		emollient	n/a	I	349.14(b)(7)
<b>wheat germ</b>						
	miscellaneous internal weight control		anorectic	IISE	IISE	310.545(a)(20)

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<b>wheat germ glycerides</b>						
miscellaneous external	external analgesic		fever blister (topical)	defer	n/a	n/a
miscellaneous external	skin protectant		fever blister (topical)	defer	n/a	n/a
<b>wheat germ oil</b>						
miscellaneous external	hair growth/loss		hair grower	IIE	IIE	310.527(a)
<b>white ointment</b>						
ophthalmic	ophthalmic		emollient	I	I	349.14(b)(8)
<b>white petrolatum</b>						
====	skin protectant		skin protectant	n/a	n/a	347.10(r)
<b>white pine</b>						
cough/cold	cough/cold (expectorant)		expectorant	IIIIE	IIIIE	310.545(a)(6)(iii)
<b>white pine extract, compound</b>						
cough/cold	cough/cold (expectorant)		expectorant	IIIIE	IIIIE	310.545(a)(6)(iii)
<b>white pine syrup, compound</b>						
cough/cold	cough/cold (expectorant)		expectorant	IIISE	IIIIE	310.545(a)(6)(iii)
<b>white thyme oil [see thyme oil, white]</b>						
====	====		====	====	====	====
<b>wintergreen oil [see methyl salicylate]</b>						
====	====		====	====	====	====

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<b>witch hazel</b>						
hemorrhoidal		anorectal	astringent (external)	I	I	346.18 (b)
hemorrhoidal		anorectal	astringent (intrarectal)	I	I	346.18 (b)
miscellaneous external	external	analgesic	astringent	I	n/a	n/a
miscellaneous external	skin protectant		astringent	I	I	347.12(c)
<b>witch hazel water [see hamamelis water of xi]</b>						
=====	=====	=====	=====	=====	=====	=====
<b>woodruff</b>						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
<b>wool alcohols [see lanolin alcohols]</b>						
=====	=====	=====	=====	=====	=====	=====
<b>xanthan gum</b>						
miscellaneous internal	weight control		anorectic	IIIIE	IISE	310.545(a)(20)
<b>xylometazoline hydrochloride</b>						
cough/cold		cough/cold (nasal decongestant)	nasal decongestant	I	I	341.20(b)(10)
<b>yeast</b>						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
<b>yeast cell derivative, live</b>						
hemorrhoidal		anorectal	wound healing agent (external)	IIISE	IIISE	310.545(a)(26)(vii)

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Review Panel	Report					
hemorrhoidal	anorectal		wound healing agent (intrarectal)	IIISE	IIISE	310.545(a)(26)(vii)
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		diaper rash	defer	IIISE	pending
topical analgesic	skin protectant		wound healing agent	IIIIE	IIIIE	pending
<b>yohimbine</b>						
miscellaneous internal	aphrodisiac		aphrodisiac	IIISE	IIISE	310.528(a)
<b>yohimbine hydrochloride</b>						
miscellaneous internal	aphrodisiac		aphrodisiac	IIISE	IIISE	310.528(a)
<b>yohimbinum</b>						
miscellaneous internal	aphrodisiac		aphrodisiac	n/a	n/a	310.528(a)
<b>zinc acetate</b>						
=====	skin protectant		diaper rash	n/a	n/a	310.545(a)(18)(iii)
miscellaneous external	skin protectant		poison ivy/oak/sumac	defer	I	347.10(s)
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	IIISE	pending
topical analgesic	skin protectant		wound healing agent	IIIIE	IIIIE	310.545(a)(18)(i)(A)
topical analgesic	skin protectant		skin protectant	I	I	347.10(s)

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<b>zinc caprylate</b>						
antimicrobial II		antifungal	antifungal	IIIIE	IIIIE	310.545(a)(22)(ii)
<b>zinc carbonate</b>						
====		skin protectant	diaper rash	defer	IIISE	310.545(a)(18)(iii)
====		skin protectant	poison ivy/oak/sumac	n/a	I	347.10(t)
topical analgesic		skin protectant	skin protectant	I	I	347.10(t)
<b>zinc chloride</b>						
miscellaneous external	corn/callus remover		corn/callus remover	IIIIE	IIIIE	[55 FR 33261]
miscellaneous external	external analgesic		astringent	IIISE	n/a	pending
miscellaneous external	skin protectant		astringent	IIISE	IIISE	310.545(a)(18)(ii)
oral cavity	oral health care		astringent	I	I	pending
<b>zinc citrate</b>						
====	gingivitis/plaque		antiplaque/gingivitis	n/a	IIIIE	pending
<b>zinc oxide</b>						
====	n/a		sunscreen	n/a	I	352.10(r)
====	skin protectant		poison ivy/oak/sumac	n/a	I	347.10(u)
antimicrobial II	acne		acne	IIE	IIE	310.545(a)(1)
hemorrhoidal	anorectal		astringent (external)	I	I	346.18 (c)
hemorrhoidal	anorectal		astringent (intrarectal)	I	I	346.18 (c)

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Review Panel	Report					
hemorrhoidal	anorectal		protectant (external)	I	I	346.14(b)(4)
hemorrhoidal	anorectal		protectant (intrarectal)	I	I	346.14(b)(4)
miscellaneous external antifungal			diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external antimicrobial			diaper rash	defer	n/a	pending
miscellaneous external boil treatment			boil treatment	IISE	IISE	310.531(a)
miscellaneous external external analgesic			astringent	IISE	IISE	pending
miscellaneous external external analgesic			diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external external analgesic			insect bite/sting	IISE	IISE	310.545(a)(10)(vi)
miscellaneous external skin protectant			astringent	IISE	IISE	310.545(a)(18)(ii)
miscellaneous external skin protectant			diaper rash	defer	I	pending
miscellaneous external skin protectant			insect bite/sting	IISE	IISE	310.545(a)(18)(v)(A)
miscellaneous external skin protectant			protectant	I	I	pending
topical analgesic	skin protectant		skin protectant	I	I	pending
<b>zinc phenolsulfonate</b>						
laxative	antidiarrheal		antidiarrheal	IIE	IIE	310.545(a)(3)(i)
laxative	antiemetic		antiemetic	IIIIE	IIE	[52 FR 15891]
miscellaneous external external analgesic			astringent	IISE	n/a	pending
miscellaneous external skin protectant			astringent	IISE	IISE	310.545(a)(18)(ii)

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<b>zinc propionate</b>						
antimicrobial II	antifungal		antifungal	IIIIE	IIIIE	310.545(a)(22)(ii)
<b>zinc pyrithione [see pyrithione zinc]</b>						
=====	=====		=====	=====	=====	=====
<b>zinc stearate</b>						
antimicrobial II	acne		acne	IIE	IIE	310.545(a)(1)
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	external analgesic		astringent	IISE	n/a	pending
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		astringent	IISE	IISE	310.545(a)(18)(ii)
miscellaneous external	skin protectant		diaper rash	defer	n/a	pending
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
<b>zinc sulfate</b>						
contraceptive/vaginal	vaginal		astringent	IIIIE	withdraw	n/a
miscellaneous external	external analgesic		astringent	IISE	n/a	pending
miscellaneous external	external analgesic		fever blister (topical)	defer	IISE	310.545(a)(10)(v)
miscellaneous external	skin protectant		astringent	IISE	IISE	310.545(a)(18)(ii)
miscellaneous external	skin protectant		fever blister (topical)	defer	IIIIE	310.545(a)(18)(iv)
miscellaneous internal	poison treatment		emetic	n/a	IISE	310.545(a)(16)

**OTC Ingredient List**  
*Updated July 2003*

<b>Ingredient</b>	<b>Review Panel</b>	<b>Report</b>	<b>Drug Category</b>	<b>ANPR</b>	<b>PR</b>	<b>FR</b>
	ophthalmic	ophthalmic	astringent	I	I	349.10
<b>zinc sulfide</b>						
antimicrobial II	acne		acne	IIE	IIE	310.545(a)(1)
<b>zinc undecylenate</b>						
antimicrobial II	antifungal		antifungal	I	I	333.210(f)
<b>zirconium oxide</b>						
miscellaneous external	external analgesic		insect bite/sting	IISE	IISE	310.545(a)(10)(vi)
miscellaneous external	skin protectant		insect bite/sting	IISE	IISE	310.545(a)(10)(vi)
miscellaneous external	skin protectant		poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
miscellaneous external	external analgesic		poison ivy/oak/sumac	n/a	IISE	310.545(a)(10)(vii)
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
<b>zyloxin</b>						
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
miscellaneous external	mercury		first aid antiseptic	IISE	n/a	310.545(a)(27)(i)
miscellaneous external	skin protectant		poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)